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about, 1072nm and/or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted to simulate the transmission spectrum of the water molecule between 980nm and 1300nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50  $\mu$ Watts/cm<sup>2</sup> and up to 2 Watts/cm<sup>2</sup>.

#### REMARKS

Applicant hereby requests further consideration of the present application in view of the amendments above and the comments that follow.

Applicant requests that the Examiner enter the foregoing amendments. Applicant submits that the amendments place the case in condition for allowance or, alternatively, in better form for appeal.

#### Status of the Claims

Claims 1 and 5-26 are pending in the application. Claims 1, 6-12 and 15-24 stand rejected under Section 102 as being anticipated by U.S. Patent No. 6,063,108 to Salansky et al. (hereinafter "Salansky"). Claims 5, 13 and 14 stand rejected under Section 103 as being unpatentable over Salansky. Claim 26 stands rejected under Section 103 as being unpatentable over Salansky in view of U.S. Patent No. 5,527,350 to Grove et al. (hereinafter "Grove"). Claim 25 stands rejected under Section 103 as being unpatentable over Salansky in view of *Lasers and Electro-Optics* by Christopher C. Davis, Cambridge University Press 1996, p. 289 (hereinafter "Davis").

#### ARGUMENTS

##### A. Legal Standards for Anticipation

Under 35 U.S.C. § 102, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987)). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research*

*Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

In some circumstances, an element may not be expressly disclosed by the prior art reference, but may be inherent in the disclosure. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" M.P.E.P. § 2112 (citations omitted) (emphasis added). Thus, the Examiner has the burden of providing extrinsic evidence establishing that (1) the alleged inherent feature is "necessarily present in the thing described in the reference", and (2) "it would be so recognized by persons of ordinary skill." In *In re Robertson*, 169 F.3d 743; 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999), the Court of Appeals for the Federal Circuit (CAFC) described these as "critical principles" informing the inherency inquiry. See, also, MPEP §2112 ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (citation omitted)).

**B. The Rejections under Sections 102 and 103**

Claim 1 as amended recites:

1. An electromagnetic radiation therapy system comprising means for emitting narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm and/or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted to simulate the

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transmission spectrum of the water molecule between 980nm and 1300nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50  $\mu\text{Watts/cm}^2$  and up to 2  $\text{Watts/cm}^2$ .

Applicant encloses herewith as **Appendix D** a graph illustrating the peak transmission through a water molecule for the Examiner's reference.

The experimental results set forth in Applicant's specification and the article submitted with Applicant's Response dated May 30, 2002 as **Appendix C** demonstrate the effectiveness of embodiments of the claimed invention and the non-obviousness of the invention as claimed. The article, in particular, reports results from an exemplary system employing means for emitting narrow band divergent electromagnetic radiation at a wavelength of 1072 nm. The article confirms the surprising observation of the effectiveness of narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072 nm hitherto not considered for herpes therapy and proposes that the effect is as a result of altered cell membrane permeability and the peak transmission spectrum of water molecules at 1072 nm.

Applicant respectfully submits that the outstanding anticipation rejection is not based on a proper analysis of the cited reference using the legal standards set forth by the CAFC or the guidance provided by the MPEP. As best understood, the Action argues essentially that each of the parameters recited in Claim 1 are subsumed within broad ranges disclosed by Salansky. As best understood, the Action acknowledges that Salansky does not teach or suggest the specifically claimed parameters themselves. As best understood, the Action further recognizes that the particular combination of parameters recited in Claim 1 are not specifically taught by Salansky. Nonetheless, the Action contends that Salansky anticipates the invention of Claim 1.

The presently-claimed system can be distinguished from the system of the cited reference, *inter alia*, on the basis that the use of narrow band divergent electromagnetic radiation centered at the claimed wavelengths coincident with peak transmissions of a water molecule, provided at the specified radiation intensities, and with total bandwidth restricted to simulate the transmission spectrum of the water molecule between 980nm and 1300nm, can provide surprisingly beneficial effects and unexpected therapeutic results as compared to the use of narrow band divergent electromagnetic radiation outside the claimed parameters but

otherwise within the ranges taught by Salansky. Salansky provides no teaching of emitting any narrow band divergent electromagnetic radiation so as to simulate the transmission spectrum of a water molecule. As such, Salansky does not teach using narrow band divergent electromagnetic radiation centered at, or about, 1072nm or 1268nm so as to coincide with peak transmissions of a water molecule. Moreover, Salansky does not teach providing such radiation at the site being treated at a radiation intensity of at least 50  $\mu\text{Watts/cm}^2$  and up to 2  $\text{Watts/cm}^2$ .

At page 2, fourth paragraph of the Action, the Action states:

The fact that Salansky does not recognize the surprising effects of any particular wavelength is immaterial to the claims unless that is specifically stated in the claim.

As understood by Applicant, the Action acknowledges that Salansky fails to teach, suggest or recognize the surprising effects of the claimed wavelengths. In an effort to comply with the Examiner's requirement, Applicant has amended Claim 1 to further recite "so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted to simulate the transmission spectrum of the water molecule between 980nm and 1300nm."

To maintain the present anticipation rejection, the Examiner has the burden of showing that each and every element of the claim is disclosed by the cited reference, either expressly or by inherency. This standard cannot be satisfied in the present case. Indeed, the Action acknowledges that the wavelengths, total bandwidths, and radiation intensities taught by Salansky and those disclosed by the present inventors are not the same. The relevant inquiry is whether the claimed subset of wavelengths, total bandwidths, and radiation intensities is disclosed, either expressly or inherently, by the cited reference. Even if Salansky discloses (by way of broad ranges) the claimed wavelengths, total bandwidths, and radiation intensities, Salansky does not disclose or suggest the particular selection of the presently recited wavelengths, total bandwidths, and radiation intensities as well as simulation of the transmission spectrum of the water molecule, and the subject invention may be readily distinguished from the cited reference on this basis.

The MPEP at § 2131.03 specifically addresses anticipation of a sub-genus by a reference disclosing a genus. Specifically, MPEP § 2131.03 states (*emphasis added*):

When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation. In order to anticipate the claims the claimed subject matter must be disclosed in the reference with "sufficient specificity to constitute an anticipation under the statute. What constitutes a "sufficient specificity" is fact dependent ... The question of "sufficient specificity" is similar to that of "clearly envisaging" a species from a generic teaching. See MPEP § 2131.02.

In the instant case, Salansky is completely silent regarding the selection of the presently claimed sub-genus of wavelengths, total bandwidths, and radiation intensities and the unexpected advantages to be achieved by the selection. Salansky clearly does not disclose the recited sub-genus with "sufficient specificity," and one of ordinary skill in the art at the time of invention would not have been able to "clearly envision" the recited sub-genus from the teachings of Salansky.

Moreover, Claim 1 has been restricted to particular wavelengths: namely, a wavelength of, or about, 1072nm and/or a wavelength of, or about, 1268nm so as to coincide with the peak transmissions of a water molecule. By contrast, Salansky clearly uses ranges of wavelengths (see column 15, lines 56-65; specifically 400 to 10,000 nm, preferably 500 to 2,000 nm, more preferably 600 to 700 nm, and most preferably 800 to 1,100 nm and 630 to 680 nm). Where wavelengths are specified throughout the specification and in Tables 1, 2, 5 and 8, they are always given as ranges. Thus, Salansky clearly does not disclose or suggest the particular wavelengths recited in Claim 1 or the deliberate use of such wavelengths with bandwidths restricted to simulate the transmission spectrum of the water molecule between 980 nm and 1300 nm.

Accordingly, for the reasons set forth above, Applicant submits that the subject matter of Claim 1 is neither disclosed nor suggested by Salansky and requests that the rejection under Section 102 be withdrawn.

Furthermore, there is no disclosure in the cited art that would have lead one of ordinary skill in the art to arrive at the invention of Claim 1 in view of Salansky. To the contrary, the cited art fail to in any manner recognize the significance of the claimed wavelengths and total bandwidths and their relationship to the peak transmissions and transmission spectrum of the water molecule between 980 nm and 1300 nm, or the specified

radiation intensities. As discussed in Applicant's Response dated May 30, 2002, there is extensive evidence that Salansky in no manner recognizes the benefits that may be provided by a system according to Claim 1. Accordingly, the invention of Claim 1 would not have been obvious in view of the cited art.

Claims 5-26 depend from Claim 1 as amended and are therefore allowable as well for at least the foregoing reasons. At least certain of the dependent claims are further distinguishable from the cited art as discussed below.

Claim 5 recites:

5. An electromagnetic radiation therapy system according to Claim 1 wherein the half angle divergence of the electromagnetic radiation is in the range 15° to 45°.

The Action concedes that Salansky does not disclose expressly the specific divergence as recited in Claim 5. However, the Action states that, pending a statement of criticality, the claimed divergence is considered to be an obvious design choice.

Claim 5 sets forth a preferred invention within the invention of Claim 1. The cited divergence of Claim 5 may provide a critical safety aspect to the claimed system. More particularly, minimum divergence may be an essential design feature to ensure there are no "hot spots" as most light sources have a small area of light emission. Salansky fails to address this concern or phenomenon. Accordingly, Applicant respectfully submits that Claim 5 is thereby further distinguishable from the cited art.

**C. Additional Comments**

Applicant wishes to clarify the statement of bandwidth as identified by the Action from the article of **Appendix C** submitted with Applicant's Response dated May 30, 2002 (*see, e.g.*, the Action at page 2, lines 12-14). The bandwidth of " $\pm 20$  nm" mentioned in the article refers to the "spectral bandwidth," which is the bandwidth in which 50% of the optical power is emitted. Salansky states, "[t]he full bandwidth of the monochromatic light to activate the healing phenomenon should not exceed 30-40 nm." (Emphasis added; column 16, lines 42-43, column 41, claim 1d, claim 3). Thus, Salansky is referring to the full or total bandwidth, which is the bandwidth in which 90% of the optical power is emitted. In fact, the


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clinical objective of the **Appendix C** article was achieved using a device with a total bandwidth of 70 nm (*i.e.*, exceeding 40 nm).

### CONCLUSION

Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



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**20792**

PATENT TRADEMARK OFFICE

### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, on August 27, 2002.



Meredith Schuessler

Date of Signature: August 27, 2002

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**VERSION WITH MARKINGS TO SHOW CHANGES**

**In the Claims:**

The claims have been amended as follows:

1. **(Twice Amended)** An electromagnetic radiation therapy system comprising means for emitting narrow band divergent electromagnetic radiation at a wavelength centered at, or about, 1072nm and/or at a wavelength centered at, or about, 1268nm so as to coincide with peak transmissions of a water molecule, the total bandwidth being restricted to simulate the transmission spectrum of the water molecule between 980nm and 1300nm, the system being capable of producing, at the site being treated, a radiation intensity of at least 50  $\mu\text{Watts/cm}^2$  and up to 2  $\text{Watts/cm}^2$ .





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Appendix D

